

C31G

Drug Class: Microbicides

Drug Description

C31G is an antimicrobial and spermicidal agent that contains two surface-active compounds, cetyl betaine (a C16 alkyl betaine) and myristamine oxide (a C14 alkyl amino oxide). [1] [2] C31G is an equimolar mixture of these two amphoteric, surface-active molecules. [3] The vaginal gel is formulated with hydroxyethyl cellulose. [4]

HIV/AIDS-Related Uses

C31G is being investigated in Phase III clinical trials as a surface-active microbicide for the prevention of HIV; it is being studied in a vaginal gel formulation.[5]

In November 2003, the FDA granted Fast Track designation for Biosyn, Inc.'s development program of 1.0% C31G vaginal gel specifically for the reduction of HIV transmission.[6]

Non-HIV/AIDS-Related Uses

C31G is a broad-spectrum antibacterial agent that shows contraceptive properties in vitro.[7] C31G displays activity against gram-positive and gram-negative bacteria, fungi, yeast, and enveloped viruses. C31G is being developed as a contraceptive and for the prevention of sexually transmitted diseases, including HIV, chlamydia, herpes, and gonorrhea.[8] C31G is also being studied in an oral rinse formulation for the prevention of oral candidiasis in cancer patients undergoing chemotherapy and in a dermatologic application for the treatment of acne, impetigo, and diabetic and decubitus ulcers.[9]

Pharmacology

The nonmetabolic mode of action of C31G is thought to give C31G an advantage over systemic drugs that inhibit specific metabolic pathways, because organisms usually develop resistance to such drugs. The C31G micelle binds to the surface of a microorganism, causing an irreversible disruption of the phospholipid membrane and resulting in destruction of the cell.[10]

C31G has been tested against several different subtypes, clades, and strains of HIV; all are equally susceptible. C31G also inhibits herpes simplex virus (HSV) -1 and -2 as measured by in vitro plaque assays. Studies in mouse xenograft models have shown that C31G inhibits transmission of HSV.[11]

In three separate Phase I studies of the safety of and tolerance to C31G, this microbicide appears to be as least as safe, acceptable, and well-tolerated as compared to a marketed spermicide (Extra Strength Gynol II) containing nonoxynol-9 (N-9). Minimal genital irritation in both men and women was observed in all three Phase I trials.[12] [13] [14] Based on clinical trial results comparing three different concentrations of C31G against the N-9 spermicide, the 0.5% and 1.0% concentrations appear to be less irritating in women than either the 1.7% concentration of C31G or the N-9 spermicide.[15] C31G demonstrated significant contraceptive activity in women at each of these concentrations, emphasizing the promising potential of C31G as a future contraceptive. Phase III trials of C31G are planned to further evaluate its contraceptive effectiveness.[16]

Two Phase III clinical trials are currently being conducted in Africa to test C31G's efficacy in the prevention of HIV transmission in women. An additional Phase III contraceptive efficacy trial has been initiated in the U.S.[17]

Adverse Events/Toxicity

In an early Phase I clinical study, 80% of the women using C31G vaginal gel experienced symptoms of vaginal burning or heat, compared to 25% of women using 2% N-9 and 5% of women using a hydroxyethyl cellulose (HEC) gel.[18]

Mild genital irritation with C31G was minimal in further studies of men and women.[19] [20] [21] Product-related adverse effects reported by men in a Phase I study who applied 1.0% C31G gel nightly at bedtime were deemed mild by the investigator.[22] In a dose-escalating study, doses of the 0.5% and 1.0% C31G gel used in women were found to be less irritating than the 1.7% dose

Adverse Events/Toxicity (cont.)

as well as 3% N-9.[23]

Clinical Trials

For information on clinical trials that involve C31G, visit the ClinicalTrials.gov web site at <http://www.clinicaltrials.gov>. In the Search box, enter: C31G AND HIV Infections.

Dosing Information

Mode of Delivery: Intravaginal.[24]

Oral.[25]

Topical application.[26]

Dosage Form: C31G is administered intravaginally via a pre-filled applicator prior to sexual intercourse.[27]

Doses of 0.5%, 1.0%, and 1.7% C31G have been tested in Phase I studies.[28] [29] The 1.0% concentration has been selected for testing in Phase III trials.[30]

Chemistry

CAS Number: 86903-77-7[31]

Physical Description: Clear, colorless, odorless gel when formulated with HEC.[32] [33]

Other Names

C-31G[34]

Savvy[35]

C 31G[36]

Further Reading

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Manufacturer Information

C31G

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For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET
- Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET

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